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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kenichiro Shiroyama

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

08/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/848,225	Applicant(s) SHIROYAMA ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 12-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 12-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-21-09;5-13-09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and response all dated 5-13-09 is acknowledged.

Claims 7 and 12-29 are pending.

Response to Arguments

The following rejection applied to claims 7 and 12-29 has been maintained for the reasons of record:

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 7 and 12-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,355,232 to Kaneko et al and EP 092852 (EP 252 submitted on PTO-1449 dated 1-27-03) in view of US 5,294,444 to Nakamura et al or Nakamura in view of Kaneko and EP 092852, and further in view of US 4,992,266 to Knoll.
3. Nakamura teaches a transparent or semi-transparent cosmetic composition comprising an amphipathic lipid, nonionic surfactant, ionic surfactant and an aqueous medium (abstract, col. 2, lines 1-18). Nakamura teaches the non-ionic surfactant of instant claim 13 (col. 3, lines 1-5 & tables 2 and 3), cholesterol and fatty acids (table 2). The amounts of ceramides, non-ionic surfactants, fatty acids and cholesterol in the composition taught by Nakamura are within the instant claimed ratios table 2). With respect to the claimed method step of mixing lipid composition while heating at 80 -120 degrees C and heating water at 80 to 100 degrees C, Nakamura teaches that the

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components of table 3 were mixed and melted at a temperature of 85- 90 degrees C (within the heating temperature of instant claims), followed by addition of hot water (Col. 4, lines 51-55). While Nakamura fails to state the specific temperature of water, absent evidence to the contrary, the term "hot water" includes boiling water, which is 100 degrees C or water as hot as 80 C. Nakamura also teaches that the compositions do not irritate the skin, as claimed (col. 1, lines 65-68).

4. Nakamura teaches ceramides, glycerocermides and ceramide derivatives, but does not teach the ceramides having the structural formula of instant claims. Nakamura fails to teach the claimed optically active compounds.

5. Kaneko teach skin and hair protective compositions comprising erythro (2S, 3R) type of ceramides having the structural formula I -VI (col. 2, lines 15 through col. 3, lines 57). In particular, the ceramides of structural formula I meets the claimed structure II of claim 15. Kaneko also suggests a combination of amphipathic surfactants such as fatty acids, fatty alcohols etc., and cholesterol or a phytosterol, in the composition (col. 3, lines 58 through col. 4, lines 28).

6. EP '852 teaches hair care compositions comprising at least one (2S,2R)-2-acylaminoalkane-1,3-diol compounds of formula I, where the variables R1 and R2 read on the variables described in the instant formula I of claim 7. In particular, the compounds that are claimed in the instant claims 18 and 21-26 are described in the compounds on page 7 of EP 852. EP also recognizes the ceramides compounds for retaining moisture and as a skin barrier ([0010]) in addition to using them for increasing the hair strength.

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7. Thus, all three references (Nakamura, EP and Kaneko) recognize the ceramides for their improved barrier functions in skin and hair applications.

8. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to replace the ceramides of Nakamura, with the optically active ceramides of Kaneko and that of EP 252 because Kaneko as well as EP 252 teach that the optically active ceramides exert remarkable water-barrier functions in skin protection compositions, as opposed to the racemates and significantly higher water holding capacity than racemates and pseudoceramides (col. 1, lines 59-67 and col. 8, lines 10-15) and improve hair strength. Thus, a skilled artisan would have expected that the ceramides of Kaneko to function better than the ceramides or pseudoceramides of Nakamura. While Kaneko fails to teach the specific ceramides of claims 18-20, in the absence of establishing an unexpected result with respect to the specific active ceramides taught by Kaneko, one of an ordinary skill in the art at the time of the instant invention was made would understand from the teachings of Kaneko and EP that the 2S, 3R type of ceramides (optically active) are significantly more efficient in their skin moisturizing effect than the racemates and pseudoceramides because Kaneko teaches that the water restraining capacity of optically active ceramides is higher than the other ceramides (col. 8, lines 18-56).

9. *Instant claims have been amended to recite the newly added limitations "suitable for use in cosmetics" and "composition being free of an ionic surface active agent". While the limitation "for use in cosmetics" is an intended use and does not carry patentable limitations, the compositions of each of the cited prior art (above) is clearly*

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employed in cosmetic art and hence are suitable for use in cosmetics. With respect to the exclusion of the ionic surface active agents, applicants have not shown any unexpected advantages of excluding ionic surfactant from the composition. On the other hand, the instant specification clearly states that one can employ anionic surfactants (including those described by Nakamura or EP 852). Furthermore, US 266 to Knoll teaches that anionic surfactants containing sulfate or sulfonate functional groups conventionally used in several shampoo formulations, have been known to cause irritation, such as eye irritation as well as dermal irritation (col. 1), a reason also explained in the instant specification. Therefore, it would have been within the scope of a skilled artisan to exclude the anionic surfactants of Nakamura in the preparation of transparent stable composition.

Response to Arguments

10. Applicant's arguments filed 5-13-09 have been fully considered but they are not persuasive.

11. Examiner inadvertently identified EP 852 as EP 252. A correction has been made in the above rejection.

12. Applicant traverses the rejection of record stating that Kaneko teaches a lipid composition which is to be blended into a final product and that the composition of Kaneko fails to teach all and every element of the currently presented claim 7 i.e., Kaneko's composition requires an element, a nonionic surface active agent, which is expressly excluded from the claimed subject matter, as defined in the currently presented claim 7. It is stated that in sum, Applicant respectfully submits that Kaneko

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fails to teach that the claimed composition (which is suitable to use in cosmetics) does not contain a nonionic surface active agent, contains water, and is in clear composition form.

13. Applicants' arguments are not persuasive because instant claims do not exclude nonionic surfactant and instead excludes an ionic surfactant. The argument that Kaneko fails to teach all the limitations is not persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). While on one hand applicants argue that Kaneko teaches a lipid composition which is to be blended into a final product, instant claims do not exclude employing the instant composition in to a final composition. Further, the newly added limitation "for use in cosmetics" even supports the use of the instant composition in to a final cosmetic composition by blending it with other cosmetic ingredients.

14. Applicants' argue that Kaneko fails to teach that the composition contains an aqueous medium, which corresponds to "water" recited in the claims of the instant application and also fails to teach that the composition is clear which is required in the present invention. Applicants' argument is not persuasive because applicants admit that Kaneko mentions at Examples 7-13 an aqueous medium (water). In response to the argument that Examples 7-13 of Kaneko disclose consumer products which contain the ceramide composition, and the consumer product is distinguished from the claimed composition which itself contains water, examiner explained above how the instant

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composition reads on the consumer product or does not distinguish from the consumer product of the prior art.

15. Applicants argue that EP 852 does not cure the deficiencies of Kaneko because EP 852 fails to teach the nonionic surfactant. However, instant claims do not exclude nonionic surfactant. Applicantst argue that Nakamura teaches away from the instant invention. However, the present rejection provides a motivation to exclude the anionic surfactants of Nakamura because of their skin and eye irritating properties. Besides, applicants failed to provide any unexpected advantage excluding the anionic surfactant of Nakamura.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
August 11, 2009